UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
EASTERN DIVISION

JESSICA KRAFT, individually and as parent to minors L.K., S.K., and O.K.; SHELLI SCHNEIDER, individually and as parent of minors A.S and W.S.; individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	
v.	)	JURY TRIAL DEMANDED
ESSENTIA HEALTH, JOHN DOE MANUFACTURERS, JOHN DOE DISTRIBUTOR,	)	
Defendants.	)	

CLASS ACTION COMPLAINT

Plaintiffs Jessica Kraft, individually and as parent of minors L.K., S.K., and O.K, and Shelli Schneider, individually and as parent of minors A.S. and W.S., by and through their attorneys, for their Class Action Complaint on behalf of themselves and all others similarly situated, allege as follows:

I. INTRODUCTION

1. All companies in the supply chain for time- and temperature-sensitive pharmaceutical products ("TTSPPs"), including manufacturers, distributors, and providers, are responsible for ensuring that the products are continuously stored at the proper cold temperature.

2. This responsibility is important because the exposure of vaccines and other TTSPPs to temperature outside the proper cold range – called a temperature excursion – results in reduced vaccine potency and the increased risk of vaccine-preventable diseases.

3. Since at least as early as January 2017, Essentia Health sold and administered

more than 100 TTSPs manufactured by the John Doe Manufacturers and stored and distributed by the John Doe Distributor (the "Affected Medications") to Plaintiffs, their children and putative class members. The Affected Medications were handled and stored outside the proper temperature range and thus subject to one or more temperature excursions.

4. On or about April 6, 2020, Essentia Health notified approximately 50,000 patients, allegedly in Minnesota and North Dakota, that medication or vaccines they received might have been compromised by improper temperature storage by the John Doe Distributor (who Essentia Health has not named publicly).

5. Plaintiffs and their minor children, as well as Class members, have thus been injured by paying for the Affected Medicines and associated medical visits without receiving the benefit of the bargain.

6. While Essentia Health has offered to revaccinate free of charge, Plaintiffs and class members are entitled to refunds for visits for which they did not receive proper care.

7. Moreover, free vaccines are worthless to the thousands of patients who received vaccines that cannot be re-administered, such as annual flu vaccines for the 2017, 2018 and 2019 flu seasons. In addition, patients may choose to get re-vaccinated outside the Essentia Health system and will have to bear additional out-of-pocket costs.

8. Finally, Plaintiffs and the class members will have to endure additional pain and suffering to get revaccinated, as well as aggravation and time to undergo and attend additional medical examinations.

9. Accordingly, Plaintiffs bring this action for breach of express and implied warranties, for violation of the consumer protection laws of Minnesota and North Dakota, and for restitution.

II. JURISDICTION

10. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)(2), because this is a class action in which the matter in controversy exceeds the sum of $5,000,000 and Defendant is a citizen of a State different from that of at least one Class member. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) because all claims alleged herein form part of the same case or controversy.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District and Defendant conducts business in this District and is therefore subject to personal jurisdiction in this District.

III. PARTIES

12. Plaintiff Jessica Kraft is a resident of Fargo, North Dakota and citizen of the United States. Ms. Kraft is the mother of minor children L.K., S.K., and O.K. Ms. Kraft received a flu vaccine at Essentia's South University Clinic on January 31, 2017. Ms. Kraft paid in whole or in part for this visit. On information and belief, the flu vaccine she received was distributed by John Doe Distributor to Essentia Health and was subject to the Temperature Excursion. Ms. Kraft's daughter, L.K., received the following vaccines at Essentia's South University Clinic: DTAP/HEPB/IPV, Rotavirus, and Pneumococcal. On January 31, 2017, Ms. Kraft's children L.K., S.K and O.K. received flu vaccines at the same clinic. Ms. Kraft also paid in whole or in part for these visits. On information and belief, the vaccines the Kraft children received were distributed by John Doe Distributor to Essentia Health and were subject to the Temperature Excursion. Accordingly, as a result of Essentia Health's and John Doe Distributor's actions as alleged herein, Jessica Kraft and her minor children were injured and suffered damages.

13. Plaintiff Shelli Schneider is a resident of Fargo, County of Cass, North Dakota, and citizen of the United States. Ms. Schneider is the mother of minors A.S. and W.S. On April

21, 2020, Ms. Schneider received an email from a nurse, stating "we were reviewing your child's chart to see which vaccines were affected by the temperature excursion." The nurse advised that the following immunizations were affected for her child W.S.: DTaP (administered 5/25/18), Hep A (8/24/18, 2/16/18), Hib (5/25/18), and Influenza (10/12/19, 10/26/18, 11/27/17, 10/26/17). Ms. Schneider also received: a letter dated April 7, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to A.S. were affected by the temperature excursion; a letter dated April 7, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to W.S. were affected by the temperature excursion; and a letter dated May 5, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to her were affected by the temperature excursion.

14. Defendant Essentia Health is a Minnesota corporation with its principal place of business located in Duluth, Minnesota. Essentia Health is a health system that serves patients in Minnesota, Wisconsin, and North Dakota, in 13 hospitals, 69 clinics, six long-term care facilities, three assisted living facilities, three independent living facilities, five ambulance services and one research institute. Essentia Health's registered agent is Jessica Fetzer, 3000 32nd Ave., Fargo, ND 58103.

15. John Doe Distributor Defendant is a defendant whose identity is currently unknown. According to Essentia Health, John Doe Distributor maintained a medication storage location in Fargo, North Dakota that resulted in certain vaccines and medications (the Affected Medications") being stored at temperatures outside of the range recommended by manufacturers. John Doe Distributor distributed these vaccines and medications to Essentia Health, who administered them to Plaintiffs and the Class Members. John Doe Distributor Defendant is liable as set forth herein.

16. The John Doe Manufacturer Defendants are defendants whose identities are currently unknown. According to Essentia Health, more than 100 vaccines and medicines were affected by the temperature excursion and administered to Plaintiffs and the Patient Class members. The John Doe Manufacturer Defendants manufactured, marketed, distributed and sold the Affected Medications and are liable as set forth herein.

IV. FACTS

A. Proper vaccine storage and handline is necessary to ensure potency and protection.

17. According to the Centers for Disease Control (CDC), vaccines must be stored properly from the time they are manufactured until they are administered.

18. Vaccines must be continuously stored at the proper temperature. Frozen vaccines (Varicella, MMRV, and Zoster) must be stored in a freezer between -58°F and +5°F (-50°C and -15°C). The CDC provides that all other routinely recommended vaccines should be stored in a refrigerator between 35°F and 46°F (2°C and 8°C).

19. Ensuring that vaccine quality is maintained at proper temperatures "is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers." The CDC explains that: "[a] proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine."[1]

20. The CDC has explained that "[e]xposure to temperatures outside these ranges may result in reduced vaccine potency and increased risk of vaccine-preventable diseases." The

[1] https://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html (last accessed June 23, 2020).

CDC thus recommends: “It is better to not vaccinate than to administer a dose of vaccine that has been mishandled.”[2]

21. According to the CDC, "[e]xposure to temperatures outside these ranges may result in reduced vaccine potency and increased risk of vaccine-preventable diseases."[3]

22. The World Health Organization has defined a “temperature excursion” as “[a]n excursion event in which a TTSPP [time- and temperature-sensitive pharmaceutical product] is exposed to temperatures outside the range(s) prescribed for storage and/or transport.”[4]

23. The CDC, Minnesota Department of Health, and North Dakota Department of Health recommend that any vaccine subject to a temperature excursion be segregated and marked “Do Not Use.”

B. Essentia Health administered the Affected Medications subject to temperature excursions for three years to thousands of patients.

24. In or about February 2020, Essentia allegedly took over the management, storage and distribution process for medications from John Doe Distributor.

25. It was at that time that Essentia purportedly learned that John Doe Distributor had stored certain vaccines and medications outside of the recommended temperature range, potentially impacting their effectiveness. The temperatures of those vaccines and medicines were stored outside precise temperatures – generally between 35-46 degrees Fahrenheit.

26. On or about April 6, 2020, Essentia Health notified nearly 50,000 patients that medication or vaccines they received might have been compromised by improper temperature

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[2] *Id.*
[3] *Id.*
[4] https://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1 (last accessed June 23, 2020).

storage by a wholesale drug distributor.

27. Essentia has written to patients to inform them of the possibility that injectable medications or vaccines they received might have been rendered less effective by improper storage.

28. According to an alert on Essentia's website, more than 100 refrigerated injectable medications could have been compromised.[5]

29. Essentia has also stated on its website that the medications affected may date back to September 2017. However, other Essentia Health employees have advised Plaintiffs that medications they or their children received as early as January 2017 were affected.

30. Essentia explained that the affected medications and vaccines were likely sent to Essentia Health clinics in Minnesota and North Dakota.

31. While Essentia Health has offered to revaccinate free of charge, Plaintiffs and class members are entitled to refunds for visits for which they did not receive proper care. Moreover, free vaccines are worthless to the thousands of patients who received vaccines that cannot be re-administered, such as annual flu vaccines for the 2017, 2018 and 2019 flu seasons.

32. In addition, Essentia Health has refused to disclose the identity of John Doe Distributor or the steps it has implemented to ensure that proper storage and handling of the vaccines and medications is now in place. Without such essential information, patients may choose to get re-vaccinated outside the Essentia Health system but will have to bear additional out-of-pocket costs.

33. Finally, Plaintiffs and the class members will have to endure additional pain and

[5] https://www.essentiahealth.org/alerts/medication-storage-issue/?utm_source=direct-mail&utm_campaign=medical-storage-issue-fy20 (last accessed June 18, 2020).

suffering to get revaccinated, as well as aggravation and time to undergo and attend additional medical examinations.

C. Defendants were responsible to implement Current Good Manufacturing Practices.

34. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. 21 U.S.C. § 351(a)(2)(B).

35. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

36. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse the Affected Medications.

37. Any drug not manufactured in accordance with CGMPs is deemed "adulterated and/or misbranded" and may not be distributed or sold in the United States. 21 U.S.C. §§ 331(a), 351(a)(2)(B). State common law and statutory law mirror these federal standards.

38. Moreover, the U.S. Pharmacopeia Convention (hereinafter "USP") sets forth industry standards applicable—in relevant part—to distributors. Chapter 1079, entitled "Good

Storage and Shipping Practices," specifies that: "Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following: . . . Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services."

39. USP 1079 further provides that the drug product manufacturer bears:

> primary responsibility and accountability including but not limited to the following:…
>
> · Determining proper storage and handling practices
>
> · Communicating proper storage and distribution practices though the supply chain
>
> * * *
>
> · Recalling the drug product if it is found to be adulterated in any part of the supply chain
>
> However, all organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety.

40. Here, Essentia Health discovered and disclosed that the Affected Medications were subject to temperature excursion, resulting in the destruction of their efficacy or potency.

41. Each Defendant had an obligation to take – and nothing prevented any Defendant from taking – actions to protect the efficacy and potency of the Affected Medications by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

42. Each Defendant breached their duty to provide proper storage, shipping, and temperature specifications as set forth above.

D. The Affected Medications were misbranded and adulterated because they did not maintain the efficacy or potency represented.

43. The manufacture of any misbranded or adulterated drug is prohibited under

federal law. 21 U.S.C. § 331(g).

44. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited. 21 U.S.C. § 331(a).

45. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful. 21 U.S.C. § 331(c).

46. Among the ways a drug may be adulterated and/or misbranded are:

a. "If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C.§ 351(a)(2)(B).

b. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium. . . ." 21 U.S.C.§ 351(b).

47. A drug is misbranded:

a. "If its labeling is false or misleading in any particular." Id. § 352(a)(1).

b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 352(c).

c. If the labeling does not contain, among other things, "the proportion of each active ingredient . . ." 21 U.S.C.§ 352(e)(1)(A)(ii).

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . ." 21 U.S.C. § 352(f).

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein." 21 U.S.C. § 352(g).

f. If the drug is advertised incorrectly in any manner. 21 U.S.C.§ 352(n).

g. If the drug's "packaging or labeling is in violation of an applicable regulation." 21 U.S.C.§ 352(p).

48. The Affected Medications were adulterated or misbranded as the facilities where they were held did not conform to or were not operated or administered in conformity with current good manufacturing practice.

49. The Affected Medications were adulterated or misbranded as to safety, because they did not have the strength, quality and/or purity characteristics, which they were purported or represented to possess.

50. It is unlawful to introduce a misbranded drug into interstate commerce. Thus, the Affected Medications were unlawfully distributed and sold.

51. By selling the Affected Medications in the stream of commerce, each Defendant warranted to consumers that the Affected Medications were safe and effective.

V. TOLLING/FRAUDULENT CONCEALMENT

52. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

53. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

54. The nature of Plaintiffs' injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

55. Plaintiffs bring this Complaint within the applicable statute of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' injuries and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

56. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs regarding any defects associated with the Affected Medications, including the safety, potency or efficacy of the drugs. Defendants affirmatively withheld and/or misrepresented facts concerning the manner in which the Affected Medications were distributed and sold, and the effects on the Affected Medications. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiffs had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

57. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defective manner in which the Affected Medications were stored —information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known that Defendants' Affected Medications were misbranded, adulterated and defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

VI. CLASS ALLEGATIONS

58. Plaintiffs bring this action in their individual capacity and on behalf of the following Class: "All persons who paid, in whole or in part, for or were administered the Affected Medications at Essentia Health." For purposes of this definition, the full list of Affected Medications will be supplemented upon discovery from Essentia Health.

59. Excluded from the Class are Defendants and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendants have a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation, including their immediate family members. Plaintiffs reserve the right to modify or amend the definition of the Class, including to add one or more subclasses, after having the opportunity to conduct discovery.

60. The proposed Class meets the requirements of Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3) and/or 23(c)(4).

61. ***Numerosity***. The members of the class are so numerous that joinder is impracticable. Essentia Health has stated that the Affected Medications were administered to nearly 50,000 patients.

62. ***Typicality***. Plaintiffs' claims are typical of the claims of putative Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the

claims of the other Class members. Each Plaintiff, like each Class member, paid money to purchase the Affected Medications manufactured, distributed or sold by Defendants, paid money for the medical appointment at which the Affected Medications were administered, and/or were administered the Affected Medications. Plaintiffs, like each Class member, were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the Class members.

63. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the Class members. Plaintiffs' interests and the interests of all other members of the Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

64. ***Commonality and Predominance.*** There are numerous questions of law and fact common to the Classes, and these common questions predominate over any issues affecting only individual Class members. Questions common to the Classes include, but are not limited to, the following:

a. whether the Affected Medications were subject or potentially subject to one or more temperature excursions;

b. whether each Defendant knew or should have known that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature excursions;

c. whether one or more Defendants acted to conceal the fact that that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature

excursions;

d. whether Defendants' marketing, advertising, or promotion of the Affected Medications misrepresented their efficacy or potency;

e. whether Defendants' failure to disclose that that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature excursions affecting their efficacy and potency was unfair, deceptive, fraudulent, or unconscionable;

f. whether Defendants' conduct was knowing or willful;

g. whether Defendants' conduct violated the Minnesota and North Dakota consumer-protection statutes;

h. whether Defendants breached express warranties;

i. whether Defendants breached implied warranties;

j. whether Defendants have been unjustly enriched;

k. whether Plaintiffs and the Class members are entitled to recover damages and the appropriate measure of those damages; and

l. the appropriate measure of disgorgement.

65. ***Superiority.*** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress

Defendants' wrongful conduct would be impracticable.

66. Individual litigation by each Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

67. Plaintiffs reserve the right to seek certification under Rule 23(c)(4) of common questions related to Defendants' knowledge, conduct, products, and duties.

VII. CAUSES OF ACTION

COUNT I: BREACH OF EXPRESS WARRANTIES
(Against All Defendants)

68. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

69. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the defective Affected Medications to consumers, including Plaintiffs, thereby placing the Affected Medications into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

70. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of the Affected Medications, including a duty to ensure that their products met the safety, efficacy and purity requirements of their labels. However, as alleged throughout this pleading, the ability of Defendants to properly disclose the risks associated with the Affected Medications is not limited to representations made on the labeling.

71. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels,

publications, package inserts, and other written materials intended for consumers and the general public, that the Affected Medications were effective, fit, and proper for their intended use.

72. Defendants advertised, labeled, marketed, and promoted Affected Medications, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that the Affected Medications would conform to the representations.

73. These express representations included incomplete warnings and instructions as to the lack of controls on storage and handling for the Affected Medications that resulted in the temperature excursions. Defendants knew and/or should have known that the warnings and labels did not and do not accurately or adequately set forth the risks of products that were not effective or fit for their intended purpose.

74. The representations about Affected Medications, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

75. Defendants placed Affected Medications into the stream of commerce for sale and recommended their use to consumers and the public without adequately warning of the fact that the Affected Medications were not safe, effective or fit for their intended use due to improper storage and handling.

76. Defendants breached these warranties because, among other things, Affected Medications were defective, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the

warranties in the following ways: (i) Defendants represented that the expiry dates on their products were accurate and that their Affected Medications were safe and effective throughout the end of the expiry period; and (ii) Defendants represented that their Affected Medications were effective vaccines and immunizations without disclosing that their efficacy or potency was likely to decrease completely or dramatically as a result of temperature excursions from improper storage and handling.

77. Plaintiffs detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or efficacy profile of Affected Medications in deciding to purchase the product. Plaintiffs reasonably relied upon Defendants to disclose known defects. Physicians would not have prescribed, and Plaintiffs would not have purchased or used the Affected Medications had Defendants properly disclosed the improper storage and handling of the Affected Products and resulting temperature excursions, either through advertising, labeling, or any other form of disclosure.

78. Defendants had sole access to material facts concerning the nature of the storage and handling associated with their Affected Medications, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the methods of storage and handlings were inadequate and resulting representations inaccurate.

79. Plaintiffs had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Affected Medications.

80. Plaintiffs used and/or were exposed to Affected Medications as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, or otherwise released into the stream of commerce by Defendants.

81. Defendants' breach of these express warranties were a substantial factor in

causing Plaintiffs' harm.

82. As a direct and proximate result of Defendants' breach of these warranties, as alleged herein, Plaintiffs sustained an economic loss and other injuries.

COUNT II: BREACH OF IMPLIED WARRANTIES
(Against All Defendants)

83. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

84. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Affected Medications, which were defective to consumers, including Plaintiff, thereby placing Affected Medications into the stream of commerce.

85. Before the time Plaintiffs used Affected Medications, Defendants impliedly warranted to their consumers, including Plaintiffs, that Affected Medications were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

86. But Defendants failed to disclose that Affected Medications were not effective when used as intended.

87. Plaintiffs were an intended beneficiary of the implied warranties made by Defendants to purchasers of their Affected Medications.

88. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiffs, would use Affected Medications as marketed by Defendants, which is to say that Plaintiffs were foreseeable users of Affected Medications.

89. Defendants intended that Affected Medications be used in the manner in which Plaintiffs, in fact, used them and which Defendants impliedly warranted to be of merchantable

quality, safe, and fit for this use, even though Affected Medications were not adequately stored and thus not effective.

90. In reliance upon Defendants' implied warranty, Plaintiffs used Affected Medications as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

91. Plaintiffs could not have reasonably discovered or known of the risks of serious injury associated with Affected Medications.

92. Defendants breached their implied warranty to Plaintiffs in that Affected Medications were not of merchantable quality, safe, or fit for their intended use due to their inadequate storage and cooling.

93. Defendants' breach of these implied warranties was a substantial factor in causing Plaintiffs' harm.

94. As a direct and proximate result of Defendants' breach of implied warranties, as alleged herein, Plaintiffs sustained a loss an economic loss and other injuries.

COUNT IIII: VIOLATION OF CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES LAWS
(Against All Defendants)

95. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

96. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable deceptive or fraudulent acts, or trade practices in violation of the Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68, et seq., and North Dakota Consumer Protection Law, N.D. Cent. Code §§ 51-15-01, et seq.

97. Plaintiffs used Defendants' Affected Medications and suffered ascertainable

losses as a result of Defendants' actions in violation of consumer protection laws.

98. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have paid for the Affected Medications, and would not have incurred related medical costs and injuries.

99. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiffs for Affected Medications that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

100. Unfair methods of competition or deceptive acts or practices that were proscribed by law include:

a. Representing that goods or services have characteristics, ingredients, uses benefits or qualities they do not have;

b. Representing that Affected Medications are of a particular standard, quality, and grade when they are not;

c. Advertising goods or services with the intent not to sell them as advertised;

d. Engaging in fraudulent and deceptive conduct that creates a likelihood of confusion or misunderstanding.

101. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct, which created demand for Affected Medications.

102. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Affected Medications.

103. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for Affected Medications and would not have incurred

related medical costs.

104. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to Plaintiffs constituted unfair and deceptive acts and trade practices in violation of state consumer protection statutes.

105. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

106. Plaintiffs are the type of consumers, as defined in these statutes, that these statutes were designed to protect.

107. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Affected Medications were fit to be used for the purpose for which they were intended, when in fact they were not effective or potent due to the temperature excursion, and by other acts alleged herein.

108. The actions and omissions of Defendants as alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

109. Defendants had actual knowledge of the defective condition of Affected Medications and failed to take any action to cure such defective and dangerous conditions.

110. Plaintiffs and their individual physicians relied upon Defendants' misrepresentations and omissions. Defendants' unfair or deceptive acts or practices, including

their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiffs, about the inherently defective nature of the Affected Medications.

111. Defendants had an ongoing duty to Plaintiffs to refrain from unfair and deceptive practices under these statutes in the course of their business. Specifically, Defendants owed Plaintiffs a duty to disclose all the material facts concerning the efficacy and potency (or lack thereof) of the Affected Medications because they possessed exclusive knowledge, they intentionally concealed the dangers of the temperature excursions and their effects on the Affected Medications from Plaintiffs, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

112. The facts regarding the storage and handling of the Affected Products that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs, who consider such facts to be important to their purchase decisions and medical visits with respect to Affected Medications.

113. Plaintiffs purchased Affected Medications in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding Affected Medications. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs would not have purchased the drug (or paid for the medical visit) and would not have been injured.

114. Defendants' deceptive, fraudulent and unconscionable representations to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and

practices.

115. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

116. Defendants' unlawful acts and practices complained of herein affect the public interest, as the violations regarding a widely sold drug were harmful to the general public.

117. Defendants' actions and omissions as identified in this Complaint show that Defendants acted willfully, maliciously and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages, or other applicable statutory damages including treble damages where available.

COUNT IV: UNJUST ENRICHMENT
(Against All Defendants)

118. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

119. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released the Affected Medications into the stream of commerce, and therefore owed a duty of reasonable care to provide safe and effective medications.

120. Defendants knew or should have known that the Affected Medications were not safe, effective or of the quality required to provide the protections promised by the vaccines and immunizations.

121. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the hat the Affected Medications were not safe, effective or of the quality required to provide the protections promised by the vaccines and immunizations.

122. Defendants requested and received a measurable benefit at the expense of Plaintiffs in the form of payment for their Affected Medications and/or payment for the associated medical visits.

123. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiffs conferred onto Defendants at Plaintiffs' detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiffs.

124. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

125. Plaintiffs are entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing with Defendants.

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Grant certification of the Class, appoint Plaintiffs as Class Representatives, and appoint their counsel as Class Counsel;

B. Enter judgment against Defendants and in favor of Plaintiffs;

C. Award Plaintiffs compensatory damages and any other damages allowed by law;

D. Award Plaintiffs their attorneys' fees and costs in bringing this action; and

E. Grant such other and further relief as this Court deems appropriate.

Dated: July 10, 2020

JESSICA KRAFT AND SHELLI SCHNEIDER, individually and on behalf of all others similarly situated

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JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: July 10, 2020

JESSICA KRAFT AND SHELLI SCHNEIDER, individually and on behalf of all others similarly situated, Plaintiffs

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